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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/526,152

02/24/2005

Gianfranco De Paoli Ambrosi

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EXAMINER

CHONG, YONG SOO

ART UNIT

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1617

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/526,152	<b>Applicant(s)</b> DE PAOLI AMBROSI, GIANFRANCO	
	<b>Examiner</b> YONG S. CHONG	<b>Art Unit</b> 1617	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 June 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-19 is/are pending in the application.  
     4a) Of the above claim(s) 9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 10-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Status of the Application***

This Office Action is in response to applicant's response filed on 6/26/08.

Applicant's election **with** traverse of the restriction requirement in the reply is acknowledged. The traversal is on the grounds that the method claim requires the particulars of the composition. As such it is believed that the method is not for use with a materially different product. Further, as a single search can be performed to consider all aspects of the invention and in view of the close relationship between the method and the product. This is not found persuasive because another method for treating dermatitis includes administering herbal treatments or avoidance of allergenic foods or environmental triggers. Therefore, a search for the method claims will not lead to the search for the composition. The requirement is still deemed proper and is therefore made FINAL.

Claims 1-19 are pending. Claims 1, 4, 6-19 have been amended. Claim 9 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claims 1-8, 10-19 are examined herein insofar as they read on the elected invention and species.

The terminal disclaimer filed on 4/10/08 disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of US Patent 7,169,811 has been reviewed and is accepted. The terminal disclaimer has been recorded. The obviousness double patenting rejection is hereby withdrawn.

Applicant's amendments have rendered all 112 rejections of the last Office Action moot, therefore hereby withdrawn.

Applicant's arguments with respect to the 102(b) rejection of the last Office Action have been fully considered but found not persuasive. The 102(b) rejection of the last Office Action is maintained for reasons of record and modified as a result of the claim amendments. The following new rejections will also apply.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-8, 10-19 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 21-36 of copending Application No. 10/557,923. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims recite a composition comprising triethyl citrate, hydroxyacids, tartaric acid, salicyclic acid, lactic acid, and malic acid.

Claims 1-8, 10-19 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 10-11 of copending Application No. 12/095,795. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims recite a composition comprising triethyl citrate and a second active agents with the same scope in pending claim 4.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8, 10-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Yu et al. (US Patent 5,686,489).

Yu et al. teaches compositions containing alpha hydroxyacid esters of which triethyl citrate is defined as a hydroxypolyacid ester (see group (d), col. 7, line 45 and col. 4, lines 35-65). The compositions taught by Yu et al. may contain one or more esters, as well as other topically applied, to the cutis or to membranes, agents that include antimicrobial and anti-acne agents (see col. 9, lines 34-52). Additionally, Yu et al. teaches pure triethyl citrate (100%) compositions as well as at or about many other

Art Unit: 1617

percentage ranges. In Examples 28-32, pure triethyl citrate (100%) is topically applied (col. 16, lines 43-67; col. 17, lines 1-29), whereas, additional examples illustrate other formulations using other percentages of triethyl citrate 18.3% (Examples 20 & 24), 30% (Example 1), 40% (Example 17), 50 % (Example 4) as well as ranges from at or about 1% to 5%, up to 100% at or about 20% range intervals (see col. 9, lines 63-67; col. 10, lines 1-9). Also, compositions taught by Yu et al. may be formulated for cosmetic or as an active agent (see col. 27, claim 38).

Yu et al. further teaches methods of treating aging related skin conditions comprising topically applying to skin, for a period of time sufficient to induce changes in the dermis, an alpha hydroxyacid ester, stereoisomer or racemate (claim 1) which is applied to intrinsically aged skin (claim 9), or additionally added to an alpha hydroxyacid or salt thereof (claim 20). Further comprising the method of claim 1, an additional step of topically applying a cosmetic or active agent (claim 25), which may be selected from many topical agents listed in claim 26 that includes many antibiotics (i.e. minocycline, nystatin, neomycin, kanamycin, erythromycin, tetracycline and clindamycin (col. 23, lines 29 and 34-35) as well as retinol, neomycin, tocopherol, benzoyl peroxide, and vitamin E (claim 26).

From the teachings of Yu et al., applicant's claims directed to a composition containing triethyl citrate either pure or in combination with synergists are clearly anticipated. Both Yu et al. and applicant's composition are applied topically (Yu et al., col. 10, lines 31-33; De Paoli Ambrosi, ¶9 last sentence) and are used for cutaneous pathologies—aging and bacterial-induced skin ailments. The composition found in Yu

Art Unit: 1617

et al. may be formulated by using different percentages of triethyl citrate as stated above and thus clearly anticipates applicant's claims 1-3 and 5. Likewise, the triethyl citrate composition taught by Yu et al. may also add to it, one or more topical agents listed (col. 9, lines 34-52 and col. 27, claim 32), many of which are also found in applicant's claims 4, 10 and 11, of which each depends from claims 1, 2 and 3, respectively.

It is noted that claims 1-8, 10-18 are drawn to a composition and not a method. The limitations reciting alleviating and/or treating various dermatitis infections and application to a skin portion of a user are considered intended use or preamble to the composition, therefore given little patentable weight.

It is respectfully pointed out that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish from each other. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Thus, the intended use of a composition claim will be given no patentable weight.

It is further respectfully pointed out that a preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand

Art Unit: 1617

alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). See MPEP 2111.02.

### ***Response to Arguments***

Applicant argues that the cited prior art as a whole fails to disclose a composition for the purpose of a having skin infection relieving advantages. Specifically, Yu et al. fails to teach a combination of forming a composition containing triethyl citrate as the active ingredient and applying the composition to skin portion of a user that is affected by one or more dermatitis infections. At most, Yu et al. discloses alpha hydroxyacid esters for skin aging. Yu et al. fails to provide any of these dermatitis alleviating advantages since the composition of Yu et al. is only applied specifically to portions of a user's skin having age spots, skin lines, and wrinkles.

This is not persuasive because as stated above, the pending claims are drawn to a composition and not a method, therefore the intended use or preamble is afforded little patentable weight. Yu et al. clearly teach triethyl citrate as an active agent along with various antibiotics. Applicant does not argue that the essential components of the composition are not present in Yu et al.



***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Yong S Chong/  
Examiner, Art Unit 1617

YSC